



HeartSine®

Inventor. Innovator. Lifesaver.

## EC Declaration of Conformity

Manufacturer: **HeartSine Technologies Limited**

Canberra House  
203 Airport Road West  
Belfast  
BT3 9ED

Device: **samaritan® Pediatric-Pak**

Model: **PAD-PAK-04**

Description: **Combined Battery and Electrode Cartridge**

Medical Device Classification: **Class IIb via Annex II (excluding Section 4) Full Quality Assurance System**

HeartSine Technologies declares that the HeartSine samaritan® Pediatric-Pak (PAD-PAK-04), an accessory to a therapeutic medical device in the range of Automated External Defibrillators, are designed and manufactured:

- a) in conformity with the essential requirements and provisions of the European Medical Device Directive **European Council Directive 93/42/EEC** (as amended by 2007/47/EC)
- b) under the supervision of SGS UK Ltd (Notified Body Number 0120)

**SGS UK Ltd,**  
Unit 202b Worle Parkway,  
Weston-super-Mare,  
United Kingdom, BS22 6WA

Certification	SGS Certificate Number
Council Directive 93/42/EEC	GB02/54193
ISO 13485:2003	GB02/54195
EN ISO 13485:2012	GB02/54195
ISO 9001:2008	GB02/54194

Signature

Date

16th Sept 2013.

James McGuinness  
Quality Manager  
HeartSine Technologies Ltd.

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